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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,724	01/22/2002	Peter H. Seeberger	MTV-037.01	3517
25181	7590	02/11/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,724

Applicant(s)

SEEBERGER ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 23-27 is/are allowed.
- 6) ☒ Claim(s) 11,12,16 and 17 is/are rejected.
- 7) ☒ Claim(s) 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ . 6) ☐ Other: ____.

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DETAILED ACTION

The Amendment filed November 05, 2003 has been received, entered into the record and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 10 and 11 have been amended.
2. Claims 13 and 14 have been cancelled.
3. New Claim 27 has been added.
4. Remarks drawn to 35 U.S.C. 112,102(b) and 103(a) rejections.

Claims 1-12 and 15-27 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The rejection of claims 10 has been overcome by amendment.

Claim Rejections - 35 USC § 102

The rejections of claims 23-26 and 1-4 have been overcome in view of applicants' arguments. However, the following new art rejection is made of record.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al (J. Am. Chem. Soc., 1991, 113(13), 5095-5097).

Douglas et al drawn to polymer-supported synthesis of oligosaccharides teaches a method wherein a monosaccharide comprising a bromide activated anomeric carbon (page 5096, Scheme I, structure II) is coupled to a second monosaccharide linked to a polymer support and having a hydroxyl group (page 5096, Scheme I, structure I) giving structure IIIb that has the glycosidic link between the said anomeric carbon of the first monosaccharide and the hydroxyl of the second monosaccharide. A similar method involving the use of the activating group $-\text{OC}(\text{NH})-\text{CCl}_3$ is also shown in Scheme I (see coupling of structure IV and structure V to give structure VI). The two monosaccharides used in the reaction are also not identical. This teaching of Douglas et al is seen to meet the limitations of instant claims 11 and 12.

Claim Rejections - 35 USC § 103

Applicants have overcome the rejection of Claims 11, 12, 16 and 17 under 35 U.S.C. 103(a) as being unpatentable over Khane et al in combination with Kovensky et al (Bioorganic and Medicinal Chemistry 1999, 7, 1567-1580). However, the following new rejections are made of record.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 11, 12, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Douglas et al (J. Am. Chem. Soc., 1991, 113(13), 5095-5097) in combination with Kovensky et al (Bioorganic and Medicinal Chemistry 1999, 7, 1567-1580).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11, 12, 16 and 17 are drawn to a method of preparing a glycosaminoglycan comprising reacting a mono-, di- or trisaccharide comprising an activated anomeric carbon with a second mono- or di- or trisaccharide comprising a hydroxyl or amino group to form an oligosaccharide linked to a solid support, comprising a glycosidic linkage, wherein the first or the second mono- or di- or tri-saccharide is covalently linked to the support; sulfating the hydroxyl or amino moiety of the said oligosaccharide linked to the solid support and removing

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the hydroxyl or amino protecting group from the said oligosaccharide linked to the solid support by hydrogenolysis.

Douglas et al drawn to polymer-supported synthesis of oligosaccharides teaches a method wherein a monosaccharide comprising a bromide activated anomeric carbon (page 5096, Scheme I, structure II) is coupled to a second monosaccharide linked to a polymer support and having a hydroxyl group (page 5096, Scheme I, structure I) giving structure IIIb that has the glycosidic link between the said anomeric carbon of the first monosaccharide and the hydroxyl of the second monosaccharide. A similar method involving the use of the activating group $-OC(NH)-CCl_3$ is also shown in Scheme I (see coupling of structure IV and structure V to give structure VI). The two monosaccharides used in the reaction are also not identical. This teaching of Douglas et al is seen to meet the limitations of instant claims 11 and 12. However, Douglas et al do not teach a method of sulfating the hydroxyl or amino moiety of the said oligosaccharide linked to the solid support and removing the hydroxyl or amino protecting group from the said oligosaccharide linked to the solid support by hydrogenolysis.

Kovensky et al disclose the sulfation and hydrogenolysis reactions in solution phase (scheme 3, page 1569, steps m and n).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method of Douglas and the sulfation and hydrogenolysis steps of Kovensky in a method to make glycosaminoglycans oligosaccharides involving the use of solid support with a reasonable amount of success since the methodological steps for the same are seen to be disclosed in the prior art. One of ordinary skill in the art can readily recognize that the method of Douglas lends itself to the synthesis of glycosaminoglycan oligosaccharides since the method of

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Douglas involves the use of an aminosaccharide. The sulfation and hydrogenolysis steps even though not disclosed by Douglas, can still be used as instantly claimed based on the disclosure of Kovensky. Here again one of ordinary skill in the art would recognize that sulfating a hydroxyl or amino moiety and hydrogenolysis to remove a hydroxyl or amino protecting group are reactions that take place on groups attached to the saccharide unit and can be carried out even if the saccharide is covalently attached to a solid support since the covalent link is not the one affected in the said reactions.

One of ordinary skill in the art would be motivated to do so since the use of solid phase method for the synthesis of oligosaccharides makes isolation and purification unnecessary because excess reagents and decomposition products can simply be washed away from the resin bound product (Douglas, page 5096, right column below scheme I, lines 8-11). This advantage translates into an enormous savings in terms of time, labor and cost.

Conclusion

1. Claims 11, 12, 16 and 17 are rejected.
2. Claims 15 drawn to a method of making a glycosaminoglycan involving cleavage of a covalent link between an oligosaccharide and a solid support via alkene metathesis is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
3. Claims 1-10 and 23-27 drawn to a di- and trisaccharide with limitations on the substituents X, R and R' and claims 18-22 drawn to a method of preparing an oligosaccharide comprising reacting a uronic acid glycopyranosyl acceptor comprising especially a cyclic acetal at C1 and C2 are neither taught nor fairly suggested by the prior art of record.

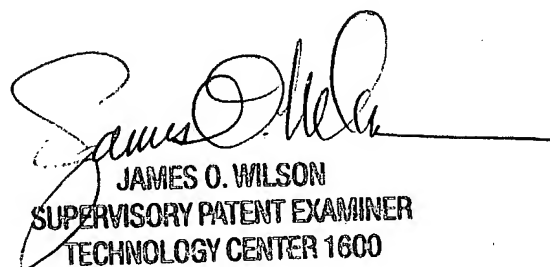
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 703-305-4837. The examiner can normally be reached on 8.30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

GK
February 8, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600